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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,289	05/11/2000	GALINA V MUKAMOLOVA	49946-60261	9774

7590 05/18/2010  
EDWARDS ANGELL PALMER & DODGE LLP  
P.O. BOX 55874  
BOSTON, MA 02205

EXAMINER
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DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<p><b>Application No.</b> 09/445,289</p>	<p><b>Applicant(s)</b> MUKAMOLOVA ET AL.</p>	
	<p><b>Examiner</b> S. Devi, Ph.D.</p>	<p><b>Art Unit</b> 1645</p>	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 05052010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires four months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☒ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: None.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 126-128, 131, 135-139, 144 and 148-159.  
Claim(s) withdrawn from consideration: 135-139 and 151-156.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

Continuation of 3. NOTE:

- 1) The dependent claim 128, as amended, includes the new limitations: 'said bacterial cell is' and 'by detecting growth of bacterial cells in the sample', which were not previously presented. These limitations raise new indefiniteness issues, requiring further consideration under 35 U.S.C § 112, second paragraph, since the claim is inconsistent in the use of pleural and non-pleural limitations: 'said bacterial cell present in a sample', 'a .... bacterial cell in the sample; and by detecting growth of 'bacterial cells in the sample'. Claim 128, as amended, further lacks proper antecedent basis in the limitation 'bacterial cells in the sample'. The limitation 'bacterial cells in the sample' is improperly broadening in scope compared to the narrower limitation 'Mycobacterium tuberculosis bacterial cells' recited in the base claim.
- 2) Claim 144, as amended, includes the new limitation: 'the bacterial cell' ... thereby resuscitating said cells, which was not previously presented. The limitation raises a new indefiniteness issue, requiring further consideration under 35 U.S.C § 112, second paragraph, since the claim is inconsistent in the pleural and non-pleural limitations: 'the bacterial cells in vitro', 'incubating the bacterial cell' and 'thereby resuscitating said cells'.
- 3) The dependent new claim 162 includes the inconsistent pleural and non-pleural limitations: 'said bacterial cells ... in a sample' and 'identifies a ... bacterial cell in the sample by detecting growth of bacterial cells in the sample', which were not previously presented. The limitation 'bacterial cells in the sample' is improperly broadening in scope compared to the narrower limitation 'Mycobacterium tuberculosis bacterial cells' recited in the base claim. These limitations raise new indefiniteness issues, requiring further consideration under 35 U.S.C § 112, second paragraph.
- 4) The new limitations in claims 128 and 162: 'the method identifies .... bacterial cell by detecting growth of bacterial cells in the sample' encompass identifying by detecting the growth of the bacterial cells in the sample without the use of an indicator, label, or a dye. Such a method lacks descriptive support in the specification, as originally filed, and raises a new matter issue, requiring further consideration at least under 35 U.S.C § 112, first paragraph.

/S. Devi/  
Primary Examiner  
AU 1645

May, 2010